Applicant's amendments and comments, received October 6, 2009, have been fully considered by the examiner. The following is a complete response to the October 6, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,001,093) in view of the teachings of Maguire et al (5,913,854).

As shown in Figures 40-45, Swanson et al disclose an ablation device comprising a tubular body (200) having a circumference and a distal end region, the tubular body having a partial curve that is adapted to change (see Figure 40). At least one ablating electrode (202) is provided along the curve and changes curve along with the tubular body (Figure 40). The electrode is configured to be flexible and to extend around only a portion of the circumference of the tubular body (see cross-sections of Figures 41A/B, 42A/B and 45). Swanson et al fail to disclose the particular manifold along the partial curve for allowing a fluid to flow through a lumen to exit the shaft at the manifold.

Maguire et al disclose an alternative ablation device comprising a catheter having a tubular body and defining a curve with electrodes located along the curve (Figure 1). In particular, Maguire et al teach that it is known to provide a fluid in communication with the electrodes, and in particular disclose a lumen for carrying the fluid through the catheter to a manifold for delivering the fluid near the electrodes. Various different

embodiments are used to deliver the fluid, including a manifold having a plurality of holes (42 – Figure 5) in communication with the fluid lumen and the ablation electrode, and including separate manifold branches which transfer fluid from the main lumen to branch lumens in communication with the electrodes (Figures 9 and 11) to allow for cooling of the RF electrodes.

To have provided the Swanson et al device with a fluid means including a lumen and a manifold for delivering a fluid to the electrode to cool the electrode during use would have been an obvious modification for one of ordinary skill in the art since Maguire et al fairly teach it is known to provide such a fluid delivery structure to cool electrodes located along a curved segment of a catheter.

Claims 1, 3-6, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,001,093) in view of the teachings of Maguire et al (5,913,854) and Burns et al (3,773,034).

The Swanson device has been addressed above. As shown in Figures 40-45, Swanson et al disclose an ablation device comprising a tubular body (200) having a circumference and a distal end region, the tubular body having a partial curve that is adapted to change (see Figure 40). At least one ablating electrode (202) is provided along the curve and changes curve along with the tubular body (Figure 40). The electrode is configured to be flexible and to extend around only a portion of the circumference of the tubular body (see cross-sections of Figures 41A/B, 42A/B and 45). Figure 45 is deemed to read on a "saw-tooth" pattern given the peaks and valleys

created by the electrode, and the electrode extends along the radius of the curve as shown in Figure 40. Regarding claims 3 and 4, Swanson disclose various "flexible and resilient" shaping elements made of stainless steel and used to steer the catheter into curved configurations. Regarding claims 10 and 11, Swanson et al do not specifically show a closed loop or open loop structure associated with the embodiment of Figures 40-45. However, earlier embodiments (Figure 27) clearly show that Swanson et al intended to create a wide range of shapes including open and closed loops. The examiner maintains that making any desired loop shape with the embodiment shown in Figures 40-45 would have been an obvious design consideration for the skilled artisan, particularly since Swanson et al clearly teach that such shapes are contemplated. Swanson fails to show the particular fluid supply lumen including a manifold, and there is no specific disclosure of an actuating lumen sealed at the distal end and used to provide fluid pressure to the lumen to cause bending of the catheter body.

Regarding the fluid flow lumen, Maguire et al teach that it is known to provide such a fluid flow means as addressed in the previous rejection.

Regarding the steering means, Burns et al teach that it is generally known to use a fluid lumen, or a plurality of fluid lumens, having a closed distal end such that a fluid pressure may be provided in the lumen(s) to cause the catheter to bend. See Abstract and column 2.

To have provided the Swanson et al catheter with an actuation lumen to control bending of the catheter via fluid pressure would have been an obvious design modification for one of ordinary skill in the art, particularly since Burns et al teach it is

known to use such an actuation lumen to control catheter bending. To have further provided a separate lumen for fluid delivery through a manifold to cool the electrodes would have been an obvious modification in view of the teaching of Maguire et al as addressed in the above rejection.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093), Maguire et al ('854) and Burns et al ('034) as applied to claim 1 above, and further in view of Maschino et al (US 6600956 B2).

Swanson et al, Maguire et al and Burns et al disclose the ablation catheter of claim 1 wherein the electrode is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Figure 40), and wherein the biased connection is biased to change the curvature of the at least partial curve along the distal end region of the tubular body. Swanson et al do not disclose an elastically deformable electrode. Maschino teaches that it is known in the medical art to form electrodes so they are elastically deformable (column 4 lines 11-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Swanson et al, as modified by the teaching of Burns et al, by making the electrodes elastically deformable so that the electrode can stretch under small stresses in order to facilitate the curving of the tubular member.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093), Maguire et al ('854) and Burns et al ('034) as applied to claim 1 above, and further in view of Kordis (5,499,981).

Swanson et al fail to disclose an interlaced electrode as set forth in these claims. Kordis discloses another ablation catheter that includes a tubular body (98) having electrodes (92) extending along a curved length of the tubular body. The electrodes are strands that are interlaced along the length of the tubular member to create an intermittently exposed series of electrodes. It is noted that Swanson et al also disclose the use of intermittent electrodes to create different lesion patterns.

To have provided the Swanson et al device, as modified by the teaching of Burns et al, with an interlaced series of electrodes to provide a flexible pattern of electrodes extending along a flexible tubular body would have been an obvious design choice for one of ordinary skill in the art in view of the teaching of Kordis.

***Response to Arguments***

Applicant's arguments, see page 7 of the response filed October 6, 2009, with respect to the rejection(s) of the claim(s) under Swanson et al and Burns et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Maguire et al.

In particular, the Maguire et al reference is deemed to provide a relevant teaching of providing a fluid to RF electrodes located on a catheter body using a lumen and a manifold to delivery the fluid directly in contact with the electrodes and tissue.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
January 5, 2010